

## **Public Health Impact of Litigation: Product Withdrawal and Reduced Innovation**

Costly and unpredictable litigation discourages innovation and can even lead to beneficial products being pulled from the market. There are several examples of this.

### ***Litigation Makes Insurance Too Expensive, Which Can Keep Valuable Drugs Off the Market***

Pharmaceutical litigation has become so costly and unpredictable that “most pharmaceutical companies have extreme difficulty obtaining basic insurance coverage in the traditional liability insurance market.” Rochelle Chodock et al., “*Insuring*” *The Continuing Solvency of Pharmaceutical Companies in the Face of Product Liability Class Actions*, 40 Tort Trial & Ins. Prac. L.J. 997, 1000 (2005). This inhibits drug development. For example:

- All but one producer of the measles vaccine stopped producing it due to astronomical insurance costs. Dick Posthumus, Editorial, *Returning Common Sense to Michigan’s Courts*, Mich. Chron., Jan. 2, 1996.
- If an AIDS vaccine is discovered, many companies may be unable to distribute it because insurance is unavailable. Kellen F. Cloney, Note, *AIDS Vaccine Manufacturers v. Tort Regime: The Need for Alternatives*, 49 Wash. & Lee L. Rev. 559, 570 (1992).

### ***Litigation Has Affected Vaccine Availability***

Liability risk has been blamed for keeping vaccines from the market. “Liability hazards led many firms to exit the vaccine market. Now there are only single-product monopolies supplying many of the vaccines for major illnesses, including polio, measles, rabies, mumps, and rubella.” W. Kip Viscusi, *Corporate Risk Analysis: A Reckless Act?*, 52 Stan. L. Rev. 547, 583 (2000).

Specific vaccines that have been withdrawn in the face of liability concerns include a Lyme disease vaccine, Lars Noah, *Triage in the Nation’s Medicine Cabinet: The Puzzling Scarcity of Vaccines and Other Drugs*, 54 S.C. L. Rev. 371, 392 (2002), and DPT vaccines made by seven different companies faced with later “discredited” claims that their vaccines caused brain damage, Stephen D. Sugarman, *Cases in Vaccine Court – Legal Battles Over Vaccines and Autism*, 357 N. Engl. J. Med. 1275, 1276 (2007).

### ***Contraceptives Research Has Been Inhibited by Litigation:***

According to the National Science Foundation, tort litigation has deterred pharmaceutical companies from researching new methods of contraception. See Nat’l Research Council, Institute of Medicine, *Developing New Contraceptives: Obstacles and Opportunities* 141 (1990). For example, one manufacturer stopped making “the Copper-7 contraceptive device after spending \$1.5 million to defend itself against four lawsuits filed in a single year.” W. Kip

Viscusi et al., *A Statistical Profile of Pharmaceutical Industry Liability, 1976-1989*, 24 Seton Hall L. Rev. 1418, 1418-19 (1994).

The result has been limited research in this field: “The number of companies conducting contraceptive research has dropped from thirteen to two.” Linda Willett, *Litigation as An Alternative to Regulation: Problems Created by Follow-On Lawsuits with Multiple Outcomes*, 18 Geo. J. Legal Ethics 1477, 1488 n.60 (2005). One commentator stated that “the United States is the only country other than Iran in which the birth control clock has been set backward.” Carl Djerassi, *The Future of Birth Control; Our Present Methods are Outdated — and Unless We Act Now, They’ll Never Be Better*, Wash. Post, Sept. 10, 1989, at C1.

### ***Unfounded Litigation Has Kept Pregnancy Medications Off the Market***

Bendectin, the only morning-sickness medicine available to women, was withdrawn from the market as a result of state law tort suits based on junk science. These lawsuits “took off after the National Enquirer published a story in October 1979 linking Bendectin, a popular morning sickness drug, with birth defects.” David E. Bernstein, *The Breast Implant Fiasco*, 87 Cal. L. Rev. 457, 460 (1999). The story was prompted by “a prominent plaintiffs’ attorney who was handling Bendectin cases.” *Id.*

Subsequent “studies clearly demonstrate that Bendectin has no measurable reproductive risks to the mother or the fetus.” Robert Brent, *Medical, Social, and Legal Implications of Treating Nausea and Vomiting of Pregnancy*, 186 Am. J. Obstetrics & Gynecology S262, S262-63 (2002). But even though the manufacturer won two-thirds of its trials, litigation costs forced it to stop selling the drug. Joseph Sanders, *From Science to Evidence: The Testimony on Causation in the Bendectin Cases*, 46 Stan. L. Rev. 1, 7 (1993).

Without Bendectin, “hospital admission for morning sickness [has] doubled.” Richard B. Stewart, *Regulatory Compliance as a Defense to Product Liability*, 88 Geo. L.J. 2167, 2171 (2000). The failure to treat severe morning sickness has an adverse effect on fetal nutrition and increases the risk of pregnancy complications. Brent at S264.